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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,906	03/17/2004	Gary K. Michelson	101.0058-03000	5309
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MARTIN & FERRARO, LLP 1557 LAKE O'PINES STREET, NE HARTVILLE, OH 44632			EXAMINER SHAFFER, RICHARD R	
			ART UNIT 3733	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/802,906	<b>Applicant(s)</b> MICHELSON, GARY K.	
	<b>Examiner</b> Richard Shaffer	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 7-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/30/2007; 12/20/2007</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The amendments to the claims filed on November 30<sup>th</sup>, 2007 are acknowledged and accepted by the examiner. The previous rejections under 35 U.S.C. 112, second paragraph are hereby withdrawn.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 7 as amended now recites, "without deformation" with regard to the locking element referring to the disclosed mechanism of rotating the locking element into a blocking relationship with the heads of the screws. There is no disclosure as originally filed stating that deformation does not take place (at least to some degree) especially in the stated possibilities of the base of the locking element acting as a cam.

Claim 42 recites numerous times the limitation, "non-elastic" with regard to the locking element; again the disclosure as originally filed does not define the locking element as either elastic or non-elastic.

Claim 47 recites, "at least a portion of said locking element .... being rigid."

Similar to claim 42, there is no disclosure defining the elasticity of the locking element in order to use terminology such as elastic, non-elastic, rigid, etc.

All dependent claims are rejected for containing new matter through inheritance of the independent claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-10, 13-16 and 18-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caesar (US Patent 2,825,329).

Caesar discloses a device (**Figures 1-3**) comprising: a low profile plate (**150**) with a substantial (broad limitation, how much is "substantial") portion of the bone-contacting surface being flat along a direction parallel to its length as well as width; at least two bone screw receiving holes (**156**) receiving bone screws (**158**) arranged side-by-side; a locking element (**140**) capable of locking the screws (**158**) either through the use as shown in **Figures 1-3** or can also merely cover the top of plate (**150**) and be rotated, slid, etc into and out of alignment for allowing the screws through holes (**156**); locking element (**140**) having a circular head (**142**) with a cut-out (as seen in **Figure 2**).

Caesar discloses all of the claimed limitations except for the use of a second locking element and thereby a second pair of bone screw receiving holes, making the

device with a fusion promoting substance such as bone or bone morphogenetic protein , and the locking element being coupled to the plate before insertion of the bone screws.

It is well known in the art to provide for a sterile package including all components to be implanted or used in a surgical procedure in order to minimize time searching for parts as well as time spent setting up the procedure. This in effect would “couple” the elements together prior to surgery. It would have been obvious to one having ordinary skill in the art at the time of invention to provide the implant components of Caesar in a sterile package to minimize surgical duration.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided for an additional locking element and plate should more than one fracture require fixation.

It would have further been obvious to one having ordinary skill in the art at the time the invention was made to use fusion promoting substances such as bone and bone morphogenetic protein (both well known in the art) to enhance bone healing.

Claims 7-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tornier (US Patent 4,488,543).

Tornier discloses a device (**Figures 1-3**) comprising: a low profile plate (**2**) with a bone contacting surface having a convex curvature along the length of the plate; **[First Interpretation]** three bone screw receiving holes (**6**) receiving bone screws (**3/3a**) arranged side-by-side; a locking element (**9** and **11** together); portion (**11**) of the locking element is elastic and thus can be pulled (partially rotated about an axis) out of the way of an inserting screw should one wish to do so; the locking element has a circular head

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(**11**) with a cutout (hole that allows **9** to pass through); [**Second Interpretation**] four bone screw receiving holes (**6** and **8**) receiving bone screws (**3/3a** and **9**); and a locking element (**11**) which can be rotated in order to allow insertion of at least two bone screws (**3/3a**).

The locking element (**11**) is also moveable without deformation from an initial position (off the plate) to a final position (on the plate) as well as rotating about an axis other than its central axis into and out of the way of the bone screw receiving holes.

Tornier discloses all of the claimed limitations except for the use of a second locking element and thereby a second pair of bone screw receiving holes, making the device with a fusion promoting substance such as bone or bone morphogenetic protein and the locking element being coupled to the plate before insertion of the bone screws.

It is well known in the art to provide for a sterile package including all components to be implanted or used in a surgical procedure in order to minimize time searching for parts as well as time spent setting up the procedure. This in effect would “couple” the elements together prior to surgery. It would have been obvious to one having ordinary skill in the art at the time of invention to provide the implant components of Tornier in a sterile package to minimize surgical duration.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided for an additional locking element and plate should more than one fracture require fixation.

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It would have further been obvious to one having ordinary skill in the art at the time the invention was made to use fusion promoting substances such as bone and bone morphogenetic protein (both well known in the art) to enhance bone healing.

### ***Double Patenting***

The following patents and patent applications have been considered for double patenting in the examination of this application:

#### **Patents:**

- 6,936,050   - 6,926,718   - 6,454,771   - 7,044,952   - 6,527,776   - 6,193,721  
- 6,936,051   - 6,398,783   - 7,041,105   - 7,077,844   - 7,118,573   - 6,383,186  
- 6,416,528   - 6,428,542   - 6,592,586   - 6,616,666   - 6,620,163   - 6,712,818  
- 6,916,320   - 6,969,390   - 7,074,221   - 7,097,645   - 7,112,202   - 7,115,130  
-6,139,550

#### **Applications:**

- 10/926,734                      - 11/110,161                      - 11/128,556

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7-51 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over:

claims 1-173 of U.S. Patent No. **6,193,721**

claims 1-39 of U.S. Patent No. **6,936,051**

claims 1-117 of U.S. Patent No. **6,398,783**

in view of Reisberg (US Patent 5,468,242).

**Comparison of Current Application against Conflicting Patents:**

**'721 Patent:** **Concave** (in dependent claims, e.g. 7, 10), **Silent** in independent claims (1, 28) instead of **convex/flat**; locking element for covering first and second bone screw receiving holes.

**'051 Patent:** **Concave** instead of **convex/flat**; lock for at least two bone screw receiving holes.

**'783 Patent:** **Concave** instead of **convex/flat**; lock for at least two bone screws (inserted in two bone screw receiving holes).

Reisberg teaches (**Column 1, Lines 5-20**) that having implants that conform to the bone surface/anatomical shape (e.g. convex, flat, and concave) is desired. One having ordinary skill in the art at the time the invention was made would have developed a device that either was pre-shaped or moldable to conform to the anatomy to provide for a low profile fit that would 1) minimize external visualization of implant and therefore



embarrassment of patient 2) irritation from inflammation 3) allow fixation members (screws, tacks, pins, etc) to have greater holding force (instead of having a significant portion hanging out of the bone). Therefore, applicant's numerous patents attempting to differentiate bone plates on the premise of concave vs. convex/flat are not novel. The mere shaping of an interface surface to conform to the intended bone to which it is to be placed is already known to be desired and beneficial.

Any additional difference between the previous patents and the current application lies in the fact that the claims (taking into account dependent claims in several) in the patents include more elements and are thus more specific. The inventions therefore define a "species" of the "generic" invention of claim 7. It has been held that the generic invention is "anticipated" by the "species." See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

Claims 7-51 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over

claims 1-72 of copending Application No. **10/926,734**

claims 1-62 of copending Application No. **11/128,556**

in view of Reisberg. As discussed in the patent section, applicant is merely reciting a concave base section with one application being "at least one" again with the other being "at least two" in regard to the bone receiving holes. Each one recites at least "two bone screws" in regard to a locking element

This is a provisional obviousness-type double patenting rejection.

***Response to Arguments***

Applicant's arguments filed November 30<sup>th</sup>, 2007 have been fully considered but they are not persuasive.

In regard to the prior art rejections over the references of Caesar and Tornier, due to the amendments in claim 7, a new rejection under 35 U.S.C. 103(a) has been applied to address the new limitation of "being coupled." As for the curvature of plate limitations, they are still deemed disclosed/taught by the prior art references either directly (Tornier) or by interpretation (Caesar). For Caesar, applicant has merely recited "a substantial portion." Any amount worth noting is "substantial" and thus many portions can be deemed "flat."

In regard to the Double Patenting rejections, applicant argues several points, which will be addressed in the same manner as set forth.

A: Applicant argues that the obviousness consideration is improper due to the base references being directed to vertebral bone plates and the teaching reference to Reisberg being directed towards a mesh implant for bone fragments. This is not found persuasive merely because as described previously, the bone plates of the conflicting patents and applications are designed for use on the spine. However, Reisberg clearly teaches that the curvature of an implant on bone depends upon the anatomy on which one intends to use it. Therefore, merely redesigning the curvature of the plate to be used on a different bony structure is obvious.

B: Applicant is taking a very narrow analysis. While the conflicting patents/applications are "for the spine", bone plates in general are for supporting bony

structures throughout the body. Thus if it's well known to design the shape according to where it is to be placed, a change in curvature of the bearing surface makes it patentably indistinct to other bone plates unless differences not based upon the shape of the bearing surface are present.

C: Applicant is misconstruing the examiner's statement. It is not to say that the conflicting patents/applications are only more specific. The comparison before the statement should be enough evidence to that effect. What is being conveyed by that statement is that any **other** difference between the current case and the conflicting patents/applications relies on the fact that they recite additional limitations therefore making them more specific in other non-consequential ways. The critical analysis is that the curvature of the plates are different due to their different intended location of implantation, which the examiner has repeatedly stated is obvious as shown by Reisberg.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard Shaffer whose telephone number is (571)272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Richard Shaffer/  
Examiner, Art Unit 3733

/Eduardo C. Robert/  
Supervisory Patent Examiner, Art Unit 3733